Single-size contraceptive diaphragm

Country of origin | United States of America

Health problem addressed

Millions of women have an unmet need for family planning. Existing contraceptives are not appropriate or acceptable for all women. Some women cannot or do not want to use hormonal methods or intrauterine devices. Diaphragms can provide safe and effective contraception but are not widely promoted for a variety of reasons.

Product description

The diaphragm is a reusable, single-size, cervical barrier made of medical-grade silicone. Its nylon spring folds easily with half the force of a standard diaphragm, making it easy to insert and remove. User input in the design process led to unique features such as the grip dimples and a finger dome to improve ease of handling and use.

Product functionality

The diaphragm is inserted into the vagina before sex to cover the cervix. It is used with a contraceptive gel to block sperm and prevent pregnancy. The single-size device fits most women. Unlike traditional-sized diaphragms that come in multiple sizes, a pelvic exam is not needed to assess size and fit of the device.

Developer's claims of product benefits

The diaphragm is a reusable, single-size, cervical barrier designed to offer the same barrier protection as a standard diaphragm with improved user acceptability. The one-size device simplifies service provision; no pelvic fit exam required to assess size. The rim bends with gentle spring force that makes the device easy to insert and remove and comfortable to wear. The fingertip removal dome allows a finger or thumb to hook the rim for removal. Silicone is more durable than latex diaphragms. The device has an overall length of 75 mm and width of 67 mm.

Operating steps

Add contraceptive gel to the cervical cup. Compress the rim by squeezing at the grip dimples. Insert the diaphragm deeply in the vagina to cover the cervix. Push the front of the device up behind the pubic bone. Wear the diaphragm at least 6 hours after sex, but no longer than 24 hours before removing to wash the device.

Development stage

The diaphragm is at late-stage clinical validation translating into early introduction and market development activities. The design is the output of a user-centered development process including women and couples from multiple sites. Safety and acceptability studies have been completed in multiple countries. The contraceptive effectiveness study has been completed; results are anticipated in 2011. Regulatory applications for Europe and the United States are in process. Production scale-up under way at manufacturing facility.

Future work and challenges

Before inserting the diaphragm women are encouraged to wash hands. Women may need coaching/training to learn about vaginal anatomy to identify the cervix and the pubic bone, the two vaginal landmarks needed for positioning. Diaphragms are recommended for use with contraceptive gel to increase effectiveness. After removing the diaphragm, the woman washes the device with soap and water, and dries it before storing it in the carrying case. Storage temperature should be between 0-40 degrees Celsius.

Use and maintenance

User: Self-user, nurse, midwife, physician

Training: Clinical studies show that women can learn to insert and correctly position the diaphragm by reading the instructions for use. However, most women report they prefer some coaching from a health care provider or another woman who has used the device to confirm correct position and use.

Maintenance: Self-user

Product specifications

Dimensions (mm): 75 x 67
Weight (kg): 0.008
Consumables: Contraceptive gel

Environment of use

Requirements: Before inserting the diaphragm women are encouraged to wash hands. Diaphragms are recommended for use with contraceptive gel to increase effectiveness. After removing the diaphragm, it needs to be washed with soap and water, and dried before storing it in the carrying case. Storage temperature should be between 0-40 degrees Celsius.

Life time: 5 years
Other features: Reusable

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